REMARKS

After entry of this amendment, claims 1-15, 23, 28, 31-33, and 50-65 are pending. The claims have been amended without prejudice or disclaimer to address various points made in the Office Action and/or to better comply with the U.S. practice. The amended claims find support *inter alia* in the original claims. Further support for the amendment made in claims 1 and 2 is found in the specification at page 4, lines 17-18, page 5, lines 25-27, page 7, lines 5-13, page 8, lines 10-12, page 9, lines 12-16, page 17, lines 21-24, and Figure 2. No new matter has been added.

Information Disclosure Statement

Pursuant to 37 CFR 1.56, 1.97 and 1.98, Applicants would like to direct the Examiner's attention to the Office Actions issued in the related application serial Nos. 10/520,210 and 11/879,143.

Claim Rejection – 35 U.S.C. § 112, Second Paragraph

Claims 1-15, 23, 28, 31-33, and 50-65 are rejected as being indefinite under 35 U.S.C. § 112, second paragraph. The Examiner alleges that the term "enhanced" is a relative term that renders the claims vague and indefinite. In light of the claim amendment specifying a basis for determining enhancement, Applicants believe that this rejection has been overcome. Reconsideration and withdrawal of the rejection is respectfully requested.

Claim Rejections – 35 U.S.C. § 112, First Paragraph

Claims 1-15, 23, 28, 31-33, and 50-65 are rejected under 35 U.S.C. § 112, first paragraph, for allegedly failing to comply with the written description requirement and for lack of an enabling disclosure. Applicants respectfully disagree and traverse the rejections.

Written Description Rejection

Claims 1-15, 23, 28, 31-33, and 50-65 are rejected for lack of adequate written description support. The Examiner alleges that the claims encompass the use of any enzymes of the methylenetetrahydrofolate (MTF) biosynthetic pathway and/or of the pantothenate biosynthetic pathway. The Examiner further asserts that the scope of each of these genuses of

enzymes includes many members with different sequence, structure, and/or enzymatic activity, but the specification fails to provide any structural features and/or biological functions that are commonly possessed by members of each genus. Office Action at pages 3-4. Applicants respectfully disagree. However, to expedite prosecution, the claims have been amended without prejudice or disclaimer to recite the genes encoding enzymes involved in deregulation of the MTF biosynthetic pathway with more specificity. Applicants respectfully request reconsideration in light of the present amendment and for the following reasons.

The "written description" requirement under 35 U.S.C. § 112, first paragraph, serves both to satisfy the inventor's obligation to disclose the technologic knowledge upon which the patent is based, and to demonstrate that the patentee was in possession of the invention that is claimed. *Capon v. Eshhar*, 418 F.3d 1349, 1357, 76 USPQ2d 1078, 1084 (Fed. Cir. 2005); *see also* MPEP § 2163. Possession may be shown in a variety of ways including description of an actual reduction to practice. *See* MPEP § 2163 (citation omitted).

Furthermore, the descriptive text needed to meet the "written description" requirement varies with the nature and scope of the invention at issue, and with the scientific and technological knowledge already in existence. *Capon*, 418 F.3d at 1357. Thus, the "written description" requirement must be applied in the context of the particular invention and the state of the knowledge. *Id* at 1358. Where information is already available in the prior art, the law does not set a *per se* rule that such information must be determined afresh. *See id* at 1358. Accordingly, when the invention does not concern the discovery of gene function or structure, rather focuses on the use of known DNA sequences of known function to achieve a novel result, the omission of the DNA sequences used in the invention from the specification does not offend the written description requirement. *See id* at 1358.

It is noted initially that the claims are not directed to the discovery of gene function but rather to a process for the enhanced production of pantothenate. Furthermore, as amended, the claims specify both the genes encoding enzymes involving in deregulation of the MTF biosynthetic pathway by their gene names as well as specific microorganisms from which the genes are derived. Thus, the claims are related to the use of known genes from known organisms

to achieve a novel result, and for that reason, extensive description of the genes themselves is not essential to describing the invention.

Moreover, the specification, by way of working examples, shows that the claimed process results in the enhanced production of pantothenate by culturing a *Bacillus* host cell transformed with a *panB* gene (Example I), a *glyA* gene (Example III), a *serA* gene (Example IV), and a disrupted *purR* gene (Example VI). The specification, therefore, provides a description of an actual reduction to practice. As such, one skilled in the art, reading the specification, would reasonably conclude that Applicants were in possession of the invention that is now claimed at the time of filing. Accordingly, the written description requirement is satisfied. Reconsideration and withdrawal of the rejection is respectfully requested.

Enablement Rejection

Claims 1-15, 23, 28, 31-33, and 50-65 are further rejected for lack of enablement. The Examiner alleges that the specification, while being enabling for a process for production of pantothenate comprising culturing a *Bacillus subtilis* host cell transformed with the plasmid pAN396 containing the *glyA* gene consisting of SEQ ID NO: 24 and the plasmid pAN824 containing the *serA* gene consisting of SEQ ID NO: 31, does not provide enablement for any other embodiment as recited in the claims. The Examiner further asserts that undue experimentation would be required to make and use the invention as claimed. Office Action at pages 5-7. Applicants respectfully disagree and traverse the rejection in view of the present amendment and further in view of the following reasons.

As discussed above, the specification, by way of working examples, describes how to make and use the claimed process for the enhanced production of pantothenate by culturing a *Bacillus* host cell transformed with a *panB* gene (Example I), a *glyA* gene (Example III), a *serA* gene (Example IV), and a disrupted *purR* gene (Example VI), illustrating an actual reduction to practice. Thus, the "presence or absence of working examples" *Wands* factor clearly supports enablement.

Moreover, the specification provides detailed guidance on how to isolate a gene involving in MTF biosynthetic pathway, how to generate an expression cassette containing such

a gene, how to transform the expression cassette into a microorganism, and how to detect the effect of the transgene expression on pantothenate production. See e.g., Examples I and III-VI. Additionally, methods for isolating a known gene from a known microorganism is well within the knowledge of the art and methods for transforming a cell with an expression cassette containing such a gene are also routine and known to one skilled in the art. Because of the detailed guidance provided in the specification and the knowledge of the art, it is respectfully submitted that no undue experimentation would be required for one skilled artisan to make and use the claimed process as amended with the genes that are not exemplified in the specification. As stated in *Ex parte Jackson*, under the applicable law, the test for "undue experimentation" is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed to enable the determination of how to practice a desired embodiment of the invention claimed. *Ex parte Jackson*, 217 USPQ 804, 807 (1982). On the facts of this case, the detailed guidance provided in the specification and the routine nature of the experimentation required for making and using the claimed process as amended weight in favor of finding enablement.

Accordingly, in view of the detailed description, guidance, working examples, state and knowledge of the art, and high level of skill, the specification enables the full scope of the claims without undue experimentation. On these facts, a proper analysis of the relevant factors supports enablement. *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988). Reconsideration and withdrawal of the enablement rejection is respectfully requested.

CONCLUSION

In view of the above remarks and further in view of the above amendments, Applicants respectfully request withdrawal of the rejections and allowance of the claims. If any outstanding issues remain, the Examiner is invited to telephone the undersigned at the number given below.

Accompanying this response is a petition for a one-month extension of time to and including February 10, 2009, to respond to the Office Action mailed October 10, 2008 with the required fee. No further fees are believed due. However, if a fee is due, please charge our

Deposit Account No. 03-2775, under Order No. 13311-00036-US from which the undersigned is authorized to draw.

Respectfully submitted,

By /s/ Hui-Ju Wu

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